

### **REMARKS**

Claims 26-52 are pending in the case. All pending claims have been rejected.

Claims 39-41 have been amended to recite "swine" rather than "pig" or "pigs". The term "swine" is supported throughout the specification.

Claims 31, 36 and 43 have been amended to clarify that the "said swine" is the swine produced by the process as specified.

Claims 30, 46 and 50 are canceled.

New claims 53-58 are added by amendment herein.

In amending or canceling claims, Applicant reserves the right to pursue the claims as filed or claims of differing scope in this or future application. In addition, Applicant respectfully submits that no new matter is introduced by any of these amendments and requests reconsideration of the application, the amended and new claims in light of the following remarks.

#### **Rejection Under 35 U.S.C. §112 (Paragraph 1)**

Claims 28-32, 34-41 and 43-52 were rejected under section 112, first paragraph, as not meeting the written description requirement.

The Office Action acknowledges that methods of mating animals are well known in the art but that the Applicant has failed to provide written description for animals other than pigs that are human-tropic PERV-positive and for PERV-loci, or primers or probes, capable of detecting human-tropic PERV-positive loci other than type c. The Examiner argues that neither the specification nor the art of record suggests that PERV can be found in other animal species. In response, although Applicant has initially submitted that the methods disclosed in the application are useful in breeding animals free of endogenous retroviruses regardless of the nature of the animal, in order to expedite prosecution, Applicant has amended claims 28 and 29 to recite swine as the animal used. As the Examiner has noted the specification is enabling for a process of producing a human-tropic PERV free swine from parental swine wherein at least one parental swine is a human-tropic PERV positive, these amendments obviate the rejection of these claims. The claims are amended solely to expedite prosecution and not in acquiescence to the rejection.

As to the argument that only probes for PERV-C are presented, Applicants respond that PCR primers corresponding to types A, B and C are presented in Table 3 of the application for complete genomic synthesis (see application at page 26). In light of the teaching of the application, Applicant believes that it is well within the skill in the art to produce probes for the detection of other PERVs if they are present.

In sum, the methods of the amended claims 28, 29, and claims dependent therefrom, merely recite that if one has a swine carrying PERV, then one can use the method of the claims to breed PERV-free offspring. Accordingly, Applicant requests reconsideration and withdrawal of these rejections under 35 U.S.C. §112, first paragraph.

### **Rejection Under 35 U.S.C. §102**

Claims 45-52 were rejected under section 102(b) as anticipated by Kaeffer et al (1976). The Examiner urges that Applicants concede that the D/D haplotype does not naturally contain infectious PERV (with citations to Tables 2 and 4 of the specification) and thereby concludes that a prior art showing of D/D haplotype inherently represents a swine that does not produce infectious PERV. In response, Applicant contends that this position is not correct, as swine of D/D haplotype are able to produce PERV that are human-tropic.

The specification merely utilizes D/D haplotype organisms in the experiment, which did not produce human-tropic PERV that infected the cells (here, human 293 cells) used in the experiment. However, the specification clearly demonstrates that D/D haplotype cell can contain human-tropic PERV. In support thereof, Applicant submits the attached Declaration under 37 C.F.R. 1.132 (attached hereto as Exhibit A) reciting results which demonstrate that some D/D swine examined were found to be infectious to humans. Hence, D/D haplotype does not alone dictate the lack of infectivity to humans. Applicant notes that the *Kaeffer et al* does not pertain to a D/D haplotype swine which is inherently human-tropic PERV-free. Further, Applicant has cancelled claims 46 and 50 and amended claims 45, 47 to 49 and 51 to 52 to recite a swine which has gone through inbreeding. *Kaeffer et al* does not disclose an inbred D/D haplotype swine. Accordingly, Applicant asserts that the rejection under 35 U.S.C. §102 is obviated. Claims are amended and canceled solely to expedite prosecution and not in acquiescence to the rejection.

Applicant requests reconsideration and withdrawal of the rejection under 35 U.S.C §102.

## **New Claims 53-58**

New claims 53–58 are directed to subject matter of a transplant comprising an organ, tissue or cells of a human-tropic PERV-free swine which has gone through inbreeding. Support for these new claims can be found throughout the specification. For example, p1 line 19, p10 line 12, p11 line 6. Applicant believes that no new matter is added by this amendment and requests that the new claims be entered and allowed in this application.

## **Conclusion**

Applicant submits that all of the stated ground of objection and rejection have been properly traversed, accommodated or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that a telephonic interview would expedite the favorable prosecution of this application, the undersigned would welcome the opportunity to discuss any outstanding issues, and to work with the Examiner toward placing the application in condition for allowance.

A petition for a one-month Extension of Time for Response is submitted herewith. The Commissioner is authorized to charge the fee for the petition, and any other fees associated with this communication or credit any overpayment to Deposit Account No. 03-0678.

Prompt and favorable consideration of the Amendment is respectfully solicited.

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**FIRST CLASS CERTIFICATE**

I hereby certify that this  
correspondence is being deposited  
today with the U.S. Postal Service as  
First Class Mail in an envelope  
addressed to:

**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

Alan J. Grant 6/24/03  
Alan J. Grant, Esq. Date

Respectfully submitted,

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